

## EXHIBIT 8

## RESPONSE TO SMDA OF 1990

## SUMMARY OF SAFETY AND EFFECTIVENESS DATA

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DEVICE NAME: **Pulpdent ResiLute II™**

PREDICATE DEVICE: *Pulpdent HardCore*  
*Pulpdent Resin Cement*  
*Pulpdent ResiLute*  
*Septodont RESIMENT*  
*Bisco All Bond C & B Luting Cement*  
*Cosmedent Insure*  
*Kerr Porcelite / Porcelite Dual Cure*  
*Bisco Choice Porcelain Veneer System*

DESCRIPTION AND INTENDED USE: *Pulpdent ResiLute II™* is a radiopaque, resin cement for the permanent cementation of dental inlays, crowns, bridges, veneers, posts, periodontal splints and for bonded amalgam techniques. It is supplied as a chemical-cure or dual-cure two-paste system (base and catalyst), with and without fluoride, that mixes easily, and as a single light-cured paste, also with and without fluoride. *Pulpdent ResiLute II™* has a very low film thickness and bonds to enamel, dentin, metals and ceramic. *Pulpdent ResiLute II™* conforms to ADA Specification No. 27 for Direct Filling Resins (see EXHIBIT 7); when a specification is adopted for resin cements, *Pulpdent ResiLute II™* will conform to it.

COMPARISON WITH PREDICATE PRODUCTS: *Pulpdent ResiLute II™* is substantially equivalent in composition and intended use to the above mentioned predicate products. Please see EXHIBIT 5 for the entire comparison.

SAFETY AND EFFECTIVENESS: According to the NIH Technology Assessment Conference on Effects and Side-Effects of Dental Restorative Materials, "General usage of these materials over about 20 years indicates a high benefit-to-risk ratio...both composites and glass ionomers are relatively trouble free. There is no evidence of short or long term risk...there is no suspicion of any problems after literally billions of procedures in the United States." Please see EXHIBIT 6 for the complete papers from the conference.